Screening Plant / Export Plant – EPA provided ATSDR with plans for removal of contamination at these facilities. ATSDR reviewed the plans and determined that they would be protective of public health [5]. Remediation of both of these sites is ongoing [28].

Schools – Cleanup of school grounds has occurred. Cleanup of school tracks is planned to be complete by the fall of 2002 [28].

Residential and Commercial Properties – The EPA has published a Sampling and Analysis Plan for prioritizing residential and commercial properties for cleanup. ATSDR reviewed this plan and found it would be protective of public health. To assure proper disposal of waste materials from the residential cleanup activities, EPA is constructing a special cell in the county landfill.

The contaminant screening study is underway. At the time of this report, 1,000 properties (about 1/3 of the total) have been screened. Of the screened properties, approximately 20% have vermiculite attic insulation and about 40% have visible vermiculite in gardens or yards. Fifty to 60 property owners denied EPA access for screening [28].

### ATSDR Child Health Initiative

ATSDR recognizes that infants and children may be more vulnerable to exposures than adults in communities faced with environmental contamination. Because children depend completely on adults for risk identification and management decisions, ATSDR is committed to evaluating their special interests at the site as part of the ATSDR Child Health Initiative.

The effects of asbestos on children are thought to be similar to adults. However, children may be especially vulnerable to asbestos exposures due to the following factors:

- Children are more likely to disturb fiber-laden soils or indoor dust while playing.
- Children are closer to the ground and thus more likely to breathe contaminated soils or dust.
- Children have faster breathing rates that may increase the level of exposure to asbestos.
- Children may be more at risk than people exposed later in life because of the long latency period between exposure and onset of asbestos-related respiratory disease.

Because many of the most highly contaminated areas have been addressed through emergency removals, children today have a lower risk of health effects than children in the past.

### Community Health Concerns

Community concerns about the health effects of asbestos exposure have been identified through ATSDR's activities in Libby. Concerns have been expressed during Community Advisory Group (CAG) meetings and other interactions with community members. A number of concerns were documented in EPA's community involvement plan [8]. ATSDR has also maintained a presence in Libby at EPA's Information Center and encouraged people to share concerns.

ATSDR plans to hold a public availability session to give community members another chance to share any health-related concerns about the site. This is tentatively planned for the last week in

September, 2002, shortly after the agency presents final results of the combined medical testing, updated mortality information as documented in this report, and results from the CT scan study.

The health-related concerns expressed to date are listed and addressed below:

**Concern:** *Does asbestos cause autoimmune disorders such as lupus, rheumatoid arthritis, and fibromyalgia?*

**Response:** There is not enough information at this time to determine whether asbestos causes autoimmune diseases. A number of studies have shown that the illness asbestosis is associated with immunological changes that could theoretically make a person more susceptible to autoimmune disorders. According to a recent allergy textbook, "immunologic abnormalities in animal models and patients with asbestosis include abnormal lymphocyte accumulation in the lower respiratory tract, abnormal T-lymphocyte subsets in BAL [bronchoalveolar lavage] fluid, evidence of decreased cell-mediated immunity, and diminished suppressor T cell function". The text continues, however, "Correlation of these abnormalities (systemic or local) with the clinical features of asbestosis ... has not been clearly demonstrated" [29]. In other words, it is not known at this time whether the changes are causally linked to the asbestosis or exposure to asbestos. It is also possible that people who have autoimmune abnormalities may be more likely to develop asbestos-related disease. Please see page 11 of this document for a more detailed treatment of this subject.

**Concern:** *What is the risk to residents, children, and visitors from vermiculite insulation dust potentially sifting into living spaces?*

**Response:** If the insulation does not contain asbestos, it poses no risk of asbestos-related illnesses. In addition, undisturbed insulation is not considered to pose a significant risk. However, if the insulation contains asbestos and is creating dust, the dust may contain microscopic asbestos fibers which increase the risk of asbestos-related health effects when breathed in. (Conservatively, it should be assumed that all insulation made with Libby vermiculite contains asbestos.) The exact level of risk depends on how many fibers were breathed in and how long the exposure lasted. In addition, a person's response to exposure differs and may be based upon genetic makeup and certain lifestyle activities, particularly smoking. People who suspect they have been exposed to asbestos fibers, especially if the exposure was long-term, should consult a physician experienced in occupational and environmental medicine or pulmonary medicine.

## Public Health Hazard Category

Based on the known past exposures and resulting disease rates, to protect public health it is prudent to reduce known continuing exposures to LA. ATSDR concludes that locations where LA-contaminated vermiculite has the potential to become airborne during people's normal activities pose a *current public health hazard* to the people of Libby.

ATSDR has also evaluated the cleanup actions and plans for cleanup taken by EPA. These actions, provided confirmation testing indicates effective reduction of LA levels, have been and

will be protective of public health by reducing continuing LA exposures. Areas that have been cleaned up as described are not likely to pose a hazard. Although very small amounts of asbestos may still be present, the potential for significant exposure is expected to be very small. Therefore, ATSDR characterizes these areas as *no apparent public health hazard*.

Based on historical information and current health outcome data, ATSDR concludes that the site was a *past public health hazard*. Workers at the mine, their household contacts, and people not occupationally exposed at the mine were exposed to airborne LA at unsafe levels. This exposure has resulted in significantly elevated levels of asbestos-related disease in the area.

## Conclusions

- People in the Libby area were exposed to hazardous levels of asbestos in the past.
- People in the Libby area have elevated levels of disease, and death, associated with exposure to asbestos.
- People may still be exposed to hazardous levels of asbestos near current source areas. These levels may be especially hazardous to sensitive populations, including people who have been exposed for many years already, smokers, and young children.
- The exact level of risk associated with low level exposure to asbestos cannot be determined due to uncertainties in the analysis and toxicology of Libby asbestos. However, continuing exposures to Libby asbestos pose an unacceptable risk to residents and workers who have already been exposed for many years.
- The cleanup actions undertaken by EPA are protective of public health.

## Recommendations

- EPA should continue to investigate and clean up the site to reduce or remove continuing sources of Libby asbestos.
- Conduct toxicological investigation of the risks associated with low level exposure to asbestos, specifically with the chemical makeup and fiber size of Libby asbestos. This investigation is necessary to assure that site cleanup levels remain protective.
- Conduct health education for the community, especially concerning smoking and asbestos.
- Create a registry to track former workers, their household contacts, and residents exposed to Libby asbestos.
- Continue to provide information to the community about the hazards of Libby asbestos.
- Continue to provide information on how to diagnose and treat asbestos-related diseases to the local medical community.

## Public Health Action Plan

The Public Health Action Plan for the site contains a description of actions have been or will be taken by ATSDR and/or other government agencies at the site. The purpose of the Public Health Action Plan is to ensure that this public health assessment not only identifies public health hazards, but provides a plan of action designed to mitigate and prevent adverse human health effects resulting from exposure to hazardous substances in the environment. Included is a

commitment on the part of ATSDR to follow up on this plan to ensure its implementation. The public health actions that have been completed are as follows:

- ATSDR published four health consultations evaluating public health implications related to Libby asbestos.
- ATSDR implemented two rounds of medical testing for signs of asbestos-related disease.
- ATSDR conducted a site visit to verify site conditions and gather pertinent information and data for the site.
- ATSDR and EPA maintained personnel in an information center in Libby to inform the community about site-related health and environmental activities.
- EPA conducted emergency removals of many contaminated areas in and around Libby.

The public health actions to be implemented follow:

- ATSDR will hold a public availability session to gather health concerns from the Libby community. These concerns will be addressed in the public comment release of this document.
- ATSDR will present results of the combined two rounds of medical testing performed in 2000 and 2001, the updated mortality review, and the computed tomography (CT) study to the Libby community. MDPHHS will provide ongoing medical testing in Libby to qualified individuals, with funding and technical assistance provided by ATSDR.
- ATSDR will work with MDPHHS to develop a registry to track former workers of the vermiculite mine and their household contacts. ATSDR will assess the feasibility of including other populations in the registry.
- EPA will continue investigating and cleaning up the site as needed.
- ATSDR will produce an addendum to this PHA evaluating the public health impact of the mine site (OU3). This addendum will be produced during EPA's RI activities for OU3.

ATSDR will reevaluate and expand this plan when needed. New environmental, toxicological, or health outcome data or the results of implementing the above proposed actions may determine the need for additional actions at this site.

## Site Team

Jill J. Dyken, Ph.D., P.E.
Environmental Health Scientist
Superfund Site Assessment Branch
Division of Health Assessment and Consultation

John Wheeler, Ph.D., DABT
Toxicologist
Exposure Investigation and Consultation Branch
Division of Health Assessment and Consultation

Dan Strausbaugh
Regional Representative
Region 8, Montana Office
Office of Regional Operations

Maria Teran-Maciver
Health Communication Specialist
Community Involvement Branch
Division of Health Assessment and Consultation

Kristina Larson, MHEd., CHES
Senior Health Education Specialist
Health Education Branch
Division of Health Education and Promotion

Vikas Kapil, D.O., MPH
Senior Medical Officer
Division of Health Studies
Office of the Director

## References

1. U.S. Environmental Protection Agency. Final sampling and analysis plan, remedial investigation, contaminant screening study, Libby Asbestos Site, Operable Unit 4. Denver, CO: CDM for U.S. Environmental Protection Agency. April 30, 2002.

2. Agency for Toxic Substances and Disease Registry. Health consultation for Libby Asbestos. Atlanta, GA: U.S. Department of Health and Human Services. December 22, 1999.

3. Agency for Toxic Substances and Disease Registry. Health consultation on mortality from asbestosis in Libby, Montana for Libby Asbestos site. Atlanta, GA: U.S. Department of Health and Human Services. December 12, 2000.

4. Agency for Toxic Substances and Disease Registry. Health consultation on export plant and screening plant for Libby Asbestos site. Atlanta, GA: U.S. Department of Health and Human Services. May 22, 2000.

5. Agency for Toxic Substances and Disease Registry. Health consultation on Libby export plant and screening plant removal plans. Atlanta, GA: U.S. Department of Health and Human Services. November 3, 2000.

6. U.S. Geological Survey. Bulletin 2192. Reconnaissance study of the geology of U.S. vermiculite deposits – Are asbestos minerals common constituents? Denver, CO: U.S. Department of the Interior. May 7, 2002, accessed on July 31, 2002 at: http://geology.cr.usgs.gov/pub/bulletins/b2192/

7. U.S. Census Bureau. American fact finder, data set from 2000 summary file 1, 5-digit zip code tabulation area 59923, accessed on July 3, 2002 at: http://factfinder.census.gov .

8. U.S. Environmental Protection Agency. Draft community involvement plan for Libby, MT site. Denver: U.S. Environmental Protection Agency, Region 8; December 12, 2000.

9. Lockey, J.E. et al. Pulmonary changes after exposure to vermiculite contaminated with fibrous tremolite. Am Rev Respir Dis 1984; 129:952-958.

10. McDonald, J.C. et al. Cohort study of mortality of vermiculite miners exposed to tremolite. Br J Ind Med 1986; 43:436-444.

11. McDonald, J.C. et al. Radiological survey of past and present vermiculite miners exposed to tremolite. Br J Ind Med 1986; 43:445-449.

12. Amandus, H.E. and Wheeler, R. The morbidity and mortality of vermiculite miners and millers exposed to tremolite-actinolite: Part II. Mortality. Am J Ind Med 1987; 11:15-26.

13. Schneider, A. A town left to die. Seattle Post-Intelligencer online. 1999 November 18. available at: http://seattlep-i.nwsource.com/uncivilaction/lib18.shtml

14. Agency for Toxic Substances and Disease Registry. Year 2000 medical testing of individuals potentially exposed to asbestoform minerals associated with vermiculite in Libby, Montana: a report to the community. Atlanta, GA: U.S. Department of Health and Human Services. August 23, 2001.

15. Agency for Toxic Substances and Disease Registry. Toxicological profile for asbestos (update). Atlanta: U.S. Department of Health and Human Services; September 2001.

16. Weis, C.P. (EPA). Memorandum to P. Peronard of U.S. Environmental Protection Agency, "Amphibole mineral fibers in source materials in residential and commercial areas of Libby pose an imminent and substantial endangerment to public health". Denver, CO: U.S. Environmental Protection Agency (EPA). December 20, 2001.

17. Agency for Toxic Substances and Disease Registry. Health consultation on mortality in Libby, Montana. Atlanta, GA: U.S. Department of Health and Human Services. August, 2002.

18. U.S. Environmental Protection Agency. Administrative record for Libby Asbestos superfund site export/screening plant and supplement. Denver: U.S. Environmental Protection Agency, Region 8. Provided electronically in May, 2002.

19. Midwest Research Institute. Collection, analysis, and characterization of vermiculite samples for fiber content and asbestos contamination. Kansas City: report prepared for the U.S. Environmental Protection Agency Office of Pesticides and Toxic Substances; September 1982.

20. Occupational Safety and Health Administration. Preamble to final rules for asbestos (amended 1994). III. Summary and explanation of revised standards. Accessed on July 16, 2002 at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=PREAMBLES&p_id=777

21. U.S. Environmental Protection Agency. Integrated risk information system (for asbestos). Accessed on July 31, 2002 at: http://www.epa.gov/iris/subst/0371.htm

22. Berman, D.W. and Crump, K. Methodology for conducting risk assessments at asbestos superfund sites. Part 2: Technical background document (interim version). Prepared for the U.S. Environmental Protection Agency Region 9. San Francisco (CA): February 15, 1999.

23. National Institute of Occupational Safety and Health. Online NIOSH pocket guide to chemical hazards. Accessed on July 16, 2002 at: http://www.cdc.gov/niosh/npg/npgd0000.html

24. American Conference of Government Industrial Hygienists. 2000 Threshold limit values for chemical substances and physical agents and biological exposure indices. Cincinnati (OH); 2000.

25. U.S. Environmental Protection Agency. National primary drinking water regulations. Accessed on July 16, 2002 at: http://www.epa.gov/safewater/mcl.html

26. Montana Department of Environmental Quality. Circular WQB-7. Montana numeric water quality standards. September 1999. Accessed on July 16, 2002 at: http://www.epa.gov/ost/standards/wqslibrary/mt/mt_8_wqb_7.pdf

27. Wright, R.S. et al. Fatal asbestosis 50 years after brief high intensity exposure in a vermiculite expansion plant. Am J Respir Crit Care Med 2002; 165:1145-1149.

28. Libby Community Advisory Group. Meeting summary for July 18, 2002 (report by Jim Christiansen on behalf of EPA). Accessed on August 2, 2002 at: http://www.epa.gov/region8/superfund/libby/cag020718.html

29. Middleton, E. (ed.) Allergy: principles and practice, 5th ed., p. 489. Mosby: 1998.

## Appendix A. ATSDR Plain Language Glossary of Environmental Health Terms

| | |
|---|---|
| **Absorption** | How a chemical enters a person's blood after the chemical has been swallowed, has come into contact with the skin, or has been breathed in. |
| **Acute Exposure** | Contact with a chemical that happens once or only for a limited period of time. ATSDR defines acute exposures as those that might last up to 14 days. |
| **Additive Effect** | A response to a chemical mixture, or combination of substances, that might be expected if the known effects of individual chemicals, seen at specific doses, were added together. |
| **Adverse Health Effect** | A change in body function or the structures of cells that can lead to disease or health problems. |
| **Amphibole** | A large group of silicate minerals with more than 40-50 members. The molecular structure of all amphiboles consists of two chains of $SiO_4$ molecules that are linked together at the oxygen atoms. In the earth's crust, amphibole minerals are mostly nonasbestiform; asbestiform amphiboles are relatively rare. See definitions of asbestiform, mineral, and mineral habit. |
| **Antagonistic Effect** | A response to a mixture of chemicals or combination of substances that is less than might be expected if the known effects of individual chemicals, seen at specific doses, were added together. |
| **Asbestiform** | A habit of crystal aggregates displaying the characteristics of asbestos: groups of separable, long, thin, strong, and flexible fibers often arranged in parallel in a column or in matted masses. See definitions of mineral and mineral habit. Mineralogists call asbestiform amphibole minerals by their mineral name followed by "asbestos". Thus, asbestiform tremolite is called tremolite asbestos. |
| **Asbestos** | A group of highly fibrous minerals with separable, long, thin fibers often arranged in parallel in a column or in matted masses. Separated asbestos fibers are generally strong enough and flexible enough to be spun and woven, are heat resistant, and are chemically inert. See definitions of fibrous and mineral. Currently, U.S. regulatory agencies recognize six asbestos minerals: the serpentine mineral, chrysotile; and five asbestiform amphibole minerals, actinolite asbestos, tremolite asbestos, anthophyllite asbestos, amosite asbestos (also known as asbestiform cummingtonite-grunerite), and crocidolite asbestos(also known as asbestiform riebeckite). Proposals have been made to update asbestos |

| | |
|---|---|
| | regulations to include other asbestiform amphibole minerals such as winchite asbestos and richterite asbestos. |
| **Asbestosis** | Interstitial fibrosis of the pulmonary parenchymal tissue in which asbestos bodies (fibers coated with protein and iron) or uncoated fibers can be detected. Pulmonary fibrosis refers to a scar-like tissue in the lung which does not expand and contract like normal tissue. This makes breathing difficult. Blood flow to the lung may also be decreased, and this causes the heart to enlarge. People with asbestosis have shortness of breath, often accompanied by a persistent cough. Asbestosis is a slow-developing disease that can eventually lead to disability or death in people who have been exposed to high amounts of asbestos over a long period. Asbestosis is not usually of concern to people exposed to low levels of asbestos. |
| **ATSDR** | The Agency for Toxic Substances and Disease Registry. ATSDR is a federal health agency in Atlanta, Georgia that deals with hazardous substance and waste site issues. ATSDR gives people information about harmful chemicals in their environment and tells people how to protect themselves from coming into contact with chemicals. |
| **Background Level** | An average or expected amount of a chemical in a specific environment. Or, amounts of chemicals that occur naturally in a specific environment. |
| **Bioavailability** | See **Relative Bioavailability**. |
| **Biota** | Used in public health, things that humans would eat – including animals, fish and plants. |
| **Cancer** | A group of diseases which occur when cells in the body become abnormal and grow, or multiply, out of control |
| **Cancer Slope Factor (CSF)** | The slope of the dose-response curve for cancer. Multiplying the CSF by the dose gives a prediction of excess cancer risk for a contaminant. |
| **Carcinogen** | Any substance shown to cause tumors or cancer in experimental studies. |
| **Chronic Exposure** | A contact with a substance or chemical that happens over a long period of time. ATSDR considers exposures of more than one year to be *chronic*. |
| **Cleavage Fragment** | Microscopic particles formed when large pieces of nonasbestiform amphiboles are crushed, as may occur in mining and milling of ores. Within a population of nonasbestiform amphibole cleavage fragments, a fraction of the particles may fit the definition of a fiber adopted for |

| | |
|---|---|
| | counting purposes. Populations of asbestos fibers can be readily distinguished from populations of nonasbestiform cleavage fragments, but sometimes it can be difficult to distinguish an isolated nonasbestiform cleavage fragment from an isolated asbestos fiber. See definitions of asbestiform, fiber, fibrous, and mineral habit. |
| **Completed Exposure Pathway** | See **Exposure Pathway**. |
| **Community Assistance Panel (CAP)** | A group of people from the community and health and environmental agencies who work together on issues and problems at hazardous waste sites. |
| **Comparison Value (CV)** | Concentrations of substances in air, water, food, and soil that are unlikely, upon exposure, to cause adverse health effects. Comparison values are used by health assessors to select which substances and environmental media (air, water, food and soil) need additional evaluation while health concerns or effects are investigated. |
| **Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)** | **CERCLA** was put into place in 1980. It is also known as **Superfund**. This act concerns releases of hazardous substances into the environment, and the cleanup of these substances and hazardous waste sites. This act created ATSDR and gave it the responsibility to look into health issues related to hazardous waste sites. |
| **Concentration** | How much or the amount of a substance present in a certain amount of soil, water, air, or food. |
| **Contaminant** | See **Environmental Contaminant**. |
| **Delayed Health Effect** | A disease or injury that happens as a result of exposures that may have occurred far in the past. |
| **Dermal Contact** | A chemical getting onto your skin (see **Route of Exposure**). |
| **Dose** | The amount of a substance to which a person may be exposed, usually on a daily basis. Dose is often explained as "amount of substance(s) per body weight per day". |
| **Dose / Response** | The relationship between the amount of exposure (dose) and the change in body function or health that results. |
| **Duration** | The amount of time (days, months, years) that a person is exposed to a chemical. |

| | |
|---|---|
| **Environmental Contaminant** | A substance (chemical) that gets into a system (person, animal, or the environment) in amounts higher than the **Background Level**, or what would be expected. |
| **Environmental Media** | Usually refers to the air, water, and soil in which chemicals of interest are found. Sometimes refers to the plants and animals that are eaten by humans. **Environmental Media** is the second part of an **Exposure Pathway**. |
| **US Environmental Protection Agency (EPA)** | The federal agency that develops and enforces environmental laws to protect the environment and the public's health. |
| **Epidemiology** | The study of the different factors that determine how often, in how many people, and in which people will disease occur. |
| **Exposure** | Coming into contact with a chemical substance. (For the three ways people can come in contact with substances, see **Route of Exposure.**) |
| **Exposure Assessment** | The process of finding the ways people come in contact with chemicals, how often and how long they come in contact with chemicals, and the amounts of chemicals with which they come in contact. |
| **Exposure Pathway** | A description of the way that a chemical moves from its source (where it began) to where and how people can come into contact with (or get exposed to) the chemical.<br><br>ATSDR defines an exposure pathway as having 5 parts:<br>1. Source of Contamination,<br>2. Environmental Media and Transport Mechanism,<br>3. Point of Exposure,<br>4. Route of Exposure, and<br>5. Receptor Population.<br><br>When all 5 parts of an exposure pathway are present, it is called a **Completed Exposure Pathway**. Each of these 5 terms is defined in this Glossary. |
| **Fiber** | Any slender, elongated mineral structure or particle. For the purposes of counting asbestos fibers in air samples, regulatory agencies commonly count particles that have lengths ≥5 $\mu$m and length:width ratios ≥3:1 as fibers. For detecting asbestos fibers in bulk building materials, particles with length:width ratios ≥5:1 are counted as fibers. |

| | |
|---|---|
| **Fiber-year/mL** | A cumulative exposure measure calculated by multiplying a worker's duration of exposure (measured in years) by the average air concentration during the period of exposure (measured in number of fibers/mL of air). Epidemiologic studies of groups of asbestos-exposed workers commonly express exposure in these units. |
| **Fibrous** | A mineral habit with crystals that look like fibers. A mineral with a fibrous habit is not asbestiform if the fibers are not separable and are not long, thin, strong, and flexible. |
| **Frequency** | How often a person is exposed to a chemical over time; for example, every day, once a week, twice a month. |
| **Hazardous Waste** | Substances that have been released or thrown away into the environment and, under certain conditions, could be harmful to people who come into contact with them. |
| **Health Effect** | ATSDR deals only with **Adverse Health Effects** (see definition in this Glossary). |
| **Indeterminate Public Health Hazard** | The category is used in Public Health Assessment documents for sites where important information is lacking (missing or has not yet been gathered) about site-related chemical exposures. |
| **Ingestion** | Swallowing something, as in eating or drinking. It is a way a chemical can enter your body (see **Route of Exposure**). |
| **Inhalation** | Breathing. It is a way a chemical can enter your body (see **Route of Exposure**). |
| **Interstitial** | A term used as an adjective relating to spaces within a tissue or organ. Pulmonary interstitial fibrosis refers to fibrosis (scarring) occurring within lung tissue. |
| **LOAEL** | Lowest Observed Adverse Effect Level. The lowest dose of a chemical in a study, or group of studies, that has caused harmful health effects in people or animals. |
| **Malignancy** | See **Cancer**. |
| **Mesothelioma** | Cancer of the thin lining surrounding the lung (the pleura) or the abdominal cavity (the peritoneum). Mesotheliomas are rare cancers in the general population. |
| **Mineral** | Any naturally occurring, inorganic substance with a crystal structure. |

| | |
|---|---|
| | Naturally occurring, inorganic substances without a crystal structure (such as amorphous silica) are called mineraloids. |
| **Mineral Habit** | The shape or morphology that single crystals or crystal aggregates take during crystal formation. Mineral habit is influenced by the environment during crystal formation. Habits of single crystals include prismatic, acicular, platy, and fiber. Habits of crystal aggregates include asbestiform, fibrous, lamellar, and columnar. |
| **MRL** | Minimal Risk Level. An estimate of daily human exposure – by a specified route and length of time – to a dose of chemical that is likely to be without a measurable risk of adverse, noncancerous effects. An MRL should not be used as a predictor of adverse health effects. |
| **NPL** | The National Priorities List. (Which is part of **Superfund**.) A list kept by the U.S. Environmental Protection Agency (EPA) of the most serious uncontrolled or abandoned hazardous waste sites in the country. An NPL site needs to be cleaned up or is being looked at to see if people can be exposed to chemicals from the site. |
| **NOAEL** | No Observed Adverse Effect Level. The highest dose of a chemical in a study, or group of studies, that did not cause harmful health effects in people or animals. |
| **No Apparent Public Health Hazard** | The category is used in ATSDR's Public Health Assessment documents for sites where exposure to site-related chemicals may have occurred in the past or is still occurring but the exposures are not at levels expected to cause adverse health effects. |
| **No Public Health Hazard** | The category is used in ATSDR's Public Health Assessment documents for sites where there is evidence of an absence of exposure to site-related chemicals. |
| **Parenchyma** | The functional cells or tissue of a gland or organ; for example, the lung parenchyma. The major lung parenchymal abnormality associated with exposure to asbestos is the development of scar-like tissue referred to as pulmonary interstitial fibrosis or asbestosis. |
| **PHA** | Public Health Assessment. A report or document that looks at chemicals at a hazardous waste site and tells if people could be harmed from coming into contact with those chemicals. The PHA also tells if possible further public health actions are needed. |
| **Pleura** | A thin lining or membrane around the lungs or chest cavity. This lining can become thickened or calcified in asbestos-related disease. |

| | |
|---|---|
| **Pleural** | Having to do with or involving the pleura. |
| **Pleural abnormalities** | Abnormal or diseased changes occurring in the pleura. Pleural abnormalities associated with exposure to asbestos include pleural plaques, pleural thickening or calcifications, and pleural effusion. |
| **Pleural calcification** | As a result of chronic inflammation and scarring, pleura becomes thickened and can calcify. White calcified areas can be seen on the pleura by X-ray. |
| **Pleural cavity** | The cavity, defined by a thin membrane (the pleural membrane or pleura), which contains the lungs. |
| **Pleural effusion** | Cells (fluid) can ooze or weep from the lung tissue into the space between the lungs and the chest cavity (pleural space) causing a pleural effusion. The effusion fluid may be clear or bloody. Pleural effusions may be an early sign of asbestos exposure or mesothelioma and should be evaluated. |
| **Pleural plaques** | Localized or diffuse areas of thickening of the pleura (lining of the lungs) or chest cavity. Pleural plaques are detected by chest x-ray, and appear as opaque, shiny, and rounded lesions. |
| **Pleural thickening** | Thickening or scarring of the pleura may be associated with asbestos exposure. In severe cases, the normally thin pleura can become thickened like an orange peel and restrict breathing. |
| **Plume** | A line or column of air or water containing chemicals moving from the source to areas further away. A plume can be a column or clouds of smoke from a chimney or contaminated underground water sources or contaminated surface water (such as lakes, ponds and streams). |
| **Point of Exposure** | The place where someone can come into contact with a contaminated environmental medium (air, water, food or soil). Some examples include: the area of a playground that has contaminated dirt, a contaminated spring used for drinking water, or the backyard area where someone might breathe contaminated air. |
| **Population** | A group of people living in a certain area; or the number of people in a certain area. |
| **PRP** | Potentially Responsible Party. A company, government or person that is responsible for causing the pollution at a hazardous waste site. PRP's are expected to help pay for the clean up of a site. |

| | |
|---|---|
| **Public Health Assessment(s)** | See **PHA.** |
| **Public Health Hazard** | The category is used in PHAs for sites that have certain physical features or evidence of chronic, site-related chemical exposure that could result in adverse health effects. |
| **Public Health Hazard Criteria** | PHA categories given to a site which tell whether people could be harmed by conditions present at the site. Each are defined in the Glossary. The categories are:<br>– Urgent Public Health Hazard<br>– Public Health Hazard<br>– Indeterminate Public Health Hazard<br>– No Apparent Public Health Hazard<br>– No Public Health Hazard |
| **Pulmonary interstitial fibrosis** | Scar-like tissue that develops in the lung parenchymal tissue in response to inhalation of dusts of certain types of substances such as asbestos. |
| **Receptor Population** | People who live or work in the path of one or more chemicals, and who could come into contact with them (See **Exposure Pathway**). |
| **Reference Dose (RfD)** | An estimate, with safety factors (see **safety factor**) built in, of the daily, life-time exposure of human populations to a possible hazard that is not likely to cause harm to the person. |
| **Relative Bioavailability** | The amount of a compound that can be absorbed from a particular medium (such as soil) compared to the amount absorbed from a reference material (such as water). Expressed in percentage form. |
| **Route of Exposure** | The way a chemical can get into a person's body. There are three exposure routes:<br>– breathing (also called inhalation),<br>– eating or drinking (also called ingestion), and<br>– getting something on the skin (also called dermal contact). |
| **Safety Factor** | Also called **Uncertainty Factor**. When scientists don't have enough information to decide if an exposure will cause harm to people, they use "safety factors" and formulas in place of the information that is not known. These factors and formulas can help determine the amount of a chemical that is not likely to cause harm to people. |

| | |
|---|---|
| **SARA** | The Superfund Amendments and Reauthorization Act in 1986 amended CERCLA (see **CERCLA**) and expanded the health-related responsibilities of ATSDR. CERCLA and SARA direct ATSDR to look into the health effects resulting from chemical exposures at hazardous waste sites. |
| **Sample Size** | The number of people that are needed for a health study. |
| **Sample** | A small number of people chosen from a larger population (see **Population**). |
| **Serpentinite** | Igneous or metamorphic rock chiefly composed of serpentine minerals such as chrysotile or lizardite. Chrysotile, when found, can occur in localities with serpentinite rock. |
| **Source (of Contamination)** | The place where a chemical comes from, such as a landfill, pond, creek, incinerator, tank, or drum. Contaminant source is the first part of an **Exposure Pathway**. |
| **Special Populations** | People who may be more sensitive to chemical exposures because of certain factors such as age, a disease they already have, occupation, sex, or certain behaviors (like cigarette smoking). Children, pregnant women, and older people are often considered special populations. |
| **Statistics** | A branch of the math process of collecting, looking at, and summarizing data or information. |
| **Superfund Site** | See **NPL**. |
| **Survey** | A way to collect information or data from a group of people (**population**). Surveys can be done by phone, mail, or in person. ATSDR cannot do surveys of more than nine people without approval from the U.S. Department of Health and Human Services. |
| **Synergistic Effect** | A health effect from an exposure to more than one chemical, where one of the chemicals worsens the effect of another chemical. The combined effect of the chemicals acting together are greater than the effects of the chemicals acting by themselves. |
| **Toxic** | Harmful. Any substance or chemical can be toxic at a certain dose (amount). The dose is what determines the potential harm of a chemical and whether it would cause someone to get sick. |
| **Toxicology** | The study of the harmful effects of chemicals on humans or animals. |

| | |
|---|---|
| **Tremolite asbestos** | A special form of the amphibole mineral, tremolite, that displays separable, long, thin fibers often arranged in parallel in a column or in matted masses. The fibers are generally strong enough and flexible enough to be spun and woven, are heat resistant, and are chemically inert. |
| **Tumor** | Abnormal growth of tissue or cells that have formed a lump or mass. |
| **Ultramafic rock** | Igneous rock composed chiefly of dark-colored ferromagnesian silicate minerals. Asbestiform amphiboles, when found, can occur in localities with ultramafic rock. |
| **Uncertainty Factor** | See **Safety Factor**. |
| **Urgent Public Health Hazard** | This category is used in ATSDR's Public Health Assessment documents for sites that have certain physical features or evidence of short-term (less than 1 year), site-related chemical exposure that could result in adverse health effects and require quick intervention to stop people from being exposed. |
| **Vermiculite** | A mineral belonging to the mica group of silicate minerals. Vermiculite has water molecules located between the silicate layers in the crystal structure. When heated, vermiculite expands to form a light-weight material that has been used for home and building insulation, as a soil amendment, and as a packing material. The process of heating and expanding vermiculite is called exfoliation or "popping". Raw vermiculite ore is processed to produce vermiculite concentrate, which is shipped to exfoliating plants to produce the finished vermiculite product. |

# EXHIBIT V

# MODERN SCIENTIFIC EVIDENCE

## The Law and Science of Expert Testimony

---

Volume 4

By

DAVID L. FAIGMAN
*University of California*
*Hastings College of the Law*

DAVID H. KAYE
*Arizona State University*
*College of Law*

MICHAEL J. SAKS
*Arizona State University*
*College of Law*

JOSEPH SANDERS
*University of Houston*
*Law Center*

ST. PAUL, MINN.
WEST PUBLISHING CO.
2002

been given as a reason for excluding expert testimony in mass tort [165] For example, in *Kelley v. American Heyer–Schulte Corporation*,[166] the [court] did exclude an expert's reanalysis of epidemiological evidence in part on [Rule] 403 grounds.[167] However, here as in other areas, Rule 403 rarely if ever [is] as the primary basis for exclusion. Evidence that has been excluded [because] of its potential for confusion or delay also has been declared to be [inadmissible] under Rule 702 or 703.

## [§ 35–]1.4 Individual Level Evidence: Specific Causation

The plaintiff's burden in civil cases is to prove each element of the cause [of] action by a preponderance of the evidence, usually interpreted to mean [more] with a degree of certainty exceeding fifty percent. The plaintiff's causal [proof] is in two parts: proof of general causation (does the substance in [question] cause any harm) and proof of specific causation (did the substance in [question] cause the plaintiff's injury). As discussed above, the plaintiff can [meet] the general causation burden with statistically significant epidemiological data, other, non-epidemiological data such as animal studies, or some [combination] of both. Whether the non-epidemiological data will suffice depends in large part on the quality and quantity of the epidemiological data [and] the nature and quality of the non-epidemiological evidence. While failure [to] prove general causation may foreclose the specific causation question, proof [of] general causation can not resolve the specific causation issue.[168]

Proof of specific causation in toxic tort cases is a troublesome problem for [the] courts.[169] Two aspects of the problem are worth special mention. First, [there] are several interrelated questions concerning the significance of a [relative] risk of 2.0 or more. Second, there is the ongoing problem of the [appropriate] role of "differential diagnosis" in toxic tort cases.

### § 35–1.4.1 Relative Risk

A recurring question is whether a relative risk of greater than 2.0 should, [by] itself, be sufficient for the plaintiff to get to a jury on specific causation. [The] argument supporting this position is that when the relative risk is more [than] doubled it is more likely than not that this particular plaintiff's injury

165. *Wade–Greaux*, 874 F.Supp. at 1485; [Hub]lin v. Kent General Hosp., Inc., 640 A.2d [1] (Del.1994).

166. 957 F.Supp. 873 (W.D.Tex.1997).

167. *Id.* at 881. *See In re* Paoli Railroad [Yard] PCB Litigation, 113 F.3d 444, 450 (3d [Cir.] 1997) (trial court did not abuse its discretion in excluding evidence related to plaintiffs' [exp]osure to heat-degraded PCBs and furans on [Fed]eral Rule of Evidence 403 grounds). *But see* [In re] TMI Litigation Cases Consolidated II, 922 [F.] Supp. 1038 (M.D.Pa.1996) (testimony of [med]ical doctor, that neoplasms of alleged victims of nuclear reactor accident were caused by [ion]izing radiation, was not so confusing as to [war]rant exclusion under Federal Rule of Evidence 403).

168. *Casey*, 877 F.Supp. at 1385.

169. An interesting question arises as to whether there is a lower standard of causation in some areas and whether this should impact admissibility rulings. This issue has arisen in CERCLA cases, Kalamazoo River Study Group v. Rockwell Int'l Corp., 171 F.3d 1065 (6th Cir.1999); Goodrich v. Betkoski, 99 F.3d 505 (2d Cir.1996); Freeport–McMoran v. B–B Paint Corp., 56 F.Supp.2d 823 (E.D.Mich.1999); and in FELA cases, Claar v. Burlington Northern R.R., 29 F.3d 499 (9th Cir.1994); Savage v. Union Pacific R.R., 67 F.Supp.2d 1021 (E.D.Ark.1999). Courts have generally concluded that admissibility criteria are not relaxed in these cases.

was caused by the substance in question. The argument opposing this position is in two parts: epidemiological studies frequently fail to control for confounding variables that systematically bias the true relative risk and the plaintiff may not resemble typical members of the study population.[170] Most courts that have considered the issue have concluded a plaintiff can reach a jury if she can present epidemiological studies indicating at least a doubling of the risk of injury due to exposure to a substance (relative risk of 2.0 or greater).[171]

A related question is whether the plaintiff can reach the jury when the epidemiological evidence indicates a relative risk of less than 2.0. Of course if the epidemiology fails to indicate any causal relationship, in the absence of other evidence the plaintiff's claim will fail on general causation grounds. But what if the evidence indicates a statistically significant relative risk greater than 1.0 but less than 2.0? As the Ninth Circuit noted in *Daubert*, a relative risk in this range may suggest a causal relationship, "but it actually tends to disprove legal causation, as it shows that Bendectin does not double the likelihood of birth defects."[172]

Here it is important to distinguish admissibility and sufficiency. The Second Circuit in *In re Joint E.&S. Dist. Asbestos Litig.*,[173] concluded that the argument that an epidemiological study must show a relative risk greater than 2.0 is a sufficiency argument, not an admissibility argument. Most courts would agree that the evidence is admissible,[174] but there are dissenting opinions.[175] However, even courts that would admit the evidence might stand

**170.** D.A. Freedman & P.B. Stark, *The Swine Flue Vaccine and Guillian–Barre Syndrome: A Case Study in Relative Risk and Specific Causation*, 64 No. 4 LAW & CONTEMP. PROB. 49 (2001). All discussions concerning whether a certain relative risk is sufficient to prove specific causation presume epidemiological studies that are not biased. If a study is biased, that is, its risk estimates are influenced by factors other than the substance under investigation, then unless the direction and extent of the bias are known, any inference drawn from the research may be suspect. Under these circumstances it would not be appropriate to make a specific causation determination based solely on the epidemiological research. In *Austin v. Kerr–McGee Refining Corp.*, 25 S.W.3d 280, 292 (Tex.App.2000), the court noted:

> Specific causation requires that a plaintiff show that the injured person is similar to those in the epidemiological studies, that he was exposed to the same substance, and that the exposure or dosage levels were comparable to or greater than those in the studies.

As Freedman and Stark note, when a number of studies suggest very large effects, e.g., a relative risk of 10.0, these criticisms of the 2.0 threshold lose much of their force. It is unlikely that the biases in the studies and the differences between the plaintiff and others in the research are so great that the "true" relative risk for people similar to the plaintiff falls below 2.0.

**171.** *In re* Joint Eastern & Southern Districts Asbestos Litig., 758 F.Supp. 199, 203 (S.D.N.Y.1991); DeLuca v. Merrell Dow Pharmaceuticals, 911 F.2d 941, 958–59 (3d Cir. 1990); *In re* "Agent Orange", 597 F.Supp. 740, 835–37 (E.D.N.Y.1984); Marder v. G.D. Searle & Co., 630 F.Supp. 1087 1092 (D.Md.1986); Landrigan v. Celotex Corp., 127 N.J. 404, 605 A.2d 1079, 1087 (1992); Merrell Dow Pharmaceuticals, Inc. v. Havner, 953 S.W.2d 706 (Tex. 1997). *But see* Lee v. A.C. & S, Co., 542 A.2d 352 (Del.Super.Ct.1987) (finding epidemiologist's opinion as to plaintiff's decedent's cause of death inadmissible).

**172.** *Daubert*, 43 F.3d at 1321.

**173.** 52 F.3d 1124, 1134 (2d Cir.1995).

**174.** *In re* Joint E.& S. Dist. Asbestos Litig., 52 F.3d 1124, 1134 (2d Cir.1995) (an argument that an epidemiological study must show a relative risk greater than 2.0 is a sufficiency argument not an admissibility argument). *See* Merrell Dow Pharmaceuticals, Inc. v. Havner, 953 S.W.2d 706, 718 (Tex.1997) (a relative risk of more than 2.0 is not a litmus test); McDaniel v. CSX Transportation, Inc., 955 S.W.2d 257, 263 (Tenn.1997); Pick v. American Medical Systems, 958 F.Supp. 1151, 1160 (E.D.La. 1997).

**175.** Sanderson v. International Flavors and Fragrances, Inc., 950 F.Supp. 981, 1000 (C.D.Cal.1996); Hall v. Baxter Healthcare Corp., 947 F.Supp. 1387, 1403 (D.Or.1996).

prepared to grant the defendant a directed verdict on sufficiency grounds.[176] A number of courts have noted that a relative risk of less than two could be combined with other information to show that it is more likely than not the alleged cause responsible for the plaintiff's injury.[177] As a practical matter, much depends on the size of the relative risk. It is easy to imagine a court allowing a case to go forward when all agree that the relative risk found in the epidemiological literature is 1.9[178] It is more difficult to imagine this outcome if the relative risk is 1.1. In the latter situation the court may very well conclude that as a matter of law the plaintiff's data are insufficient to sustain a jury verdict.[179]

**176.** For example, the court in *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 958 (3d Cir.1990) said:

> Hypothetically, Dr. Done may be able to testify, on the basis of adequate data and the application of reasonably reliable methodology, for example, that of women who took Bendectin and had children with birth defects, 25% of the cases of birth defects can be attributed to Bendectin exposure. This testimony would be admissible as it would be a basis from which a jury could rationally find that Bendectin could have caused Amy DeLuca's birth defects; however, it would not without more suffice to satisfy the DeLucas' burden on causation under a more likely than not standard since a fact finder could not say on the basis of this evidence alone that Amy DeLuca's birth defects were more likely than not caused by Bendectin.
>
> If New Jersey law requires the DeLucas to show that it is more likely than not that Bendectin caused Amy DeLuca's birth defects, and they are forced to rely solely on Dr. Done's epidemiological analysis in order to avoid summary judgment, the relative risk of limb reduction defects arising from the epidemiological data Done relies upon will, at a minimum, have to exceed "2."

**177.** Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1321 n. 16 (9th Cir. 1995); *Landigran*, 605 A.2d at 1087. Such data could come from a differential diagnosis, clinical data, or animal studies. Caterinicchio v. Pittsburgh Corning Corp., 127 N.J. 428, 605 A.2d 1092 (1992); *In re* Joint Eastern & Southern District Asbestos Litigation, 964 F.2d 92 (2d Cir.1992).

**178.** Grassis v. Johns–Manville Corp., 248 N.J.Super. 446, 591 A.2d 671 (N.J.Super.1991) (asbestos products allegedly causing colon cancer, wherein plaintiff's expert testified that asbestos was a "substantial factor"):

> Defendants argue that there should be a threshold of a 2.0 correlation before an expert should be permitted to rely upon an epidemiological study. They urge that only when this figure is exceeded can it be said that the particular factor is more likely than not to have produced the particular injury. This assertion proves too much. Assuming a large group of potential plaintiffs, a causative factor of 1.99 and significant evidence eliminating other known causes, defendants' proposition would still exclude the epidemiological proof. Even though the physical problems of just under one-half of the plaintiffs (without reference to the additional causative proof) would have been statistically "caused" by the factor being studied, none could recover. Yet, if a new study raised the risk factor to 2.01, all of the plaintiffs could use the study to collect damages, although for nearly one-half of the group, the risk factor was not an actual cause of the condition. This makes little sense, scientifically or legally.

*Id.* at 676.

**179.** A related question is whether an expert should be allowed to testify based on an epidemiological analysis when the expert does not report any relative risk (or odds ratio) for the data upon which he relies. The District of Columbia Circuit concluded that he could in *Ambrosini v. Labarraque*, 101 F.3d 129 (D.C.Cir.1996). In doing so, the court made a clear distinction between admissibility and sufficiency. "That Dr. Strom's testimony alone may be insufficient for the Ambrosinis to survive summary judgment does not necessarily defeat its admissibility under the 'fitness' prong of *Daubert*. Because Dr. Strom's testimony is 'sufficiently tied' to the facts at issue, we conclude that it satisfies *Daubert's* fitness prong." *Id.* at 136. If, in fact, the epidemiology data underlying this testimony is statistically significant and shows a relative risk (or odds ratio) greater than 1.0 this seems like a reasonable conclusion. Otherwise, most courts might conclude that the testimony is inadmissible as well as insufficient to support a verdict. Contrary to the court's opinion in *Ambrisini*, predicating admissibility on some indication of the strength of the epidemiological data underlying an opinion does not seem to be an unreasonable position.

RESPECTFULLY SUBMITTED,

REED SMITH LLP

James J. Restivo, Jr.
Lawrence E. Flatley
Douglas E. Cameron
James W. Bentz
435 Sixth Avenue
Pittsburgh, PA 15219
Telephone: 412.288.3131
Facsimile: 412.288.3063

SPECIAL ASBESTOS COUNSEL FOR DEBTORS

PACHULSKI, STANG, ZIEHL, YOUNG, JONES & WEINTRAUB P.C.

Scotta E. McFarland
Paula A. Galbraith

By _____

919 Market Street
Suite 1600
Wilmington, DE 19801
Telephone: 302.652.4100
Facsimile: 302.652.4400

CO-COUNSEL FOR DEBTORS

July 7, 2003

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the Appendix to W.R. Grace & Co.'s Motion For Summary Judgment was served this ____ day of July, 2003, via First-Class mail, postage prepaid to:

Edward J. Westbrook, Esquire
Richardson, Patrick, Westbrook &
Brickman, LLC
1037 Chuck Dawley Boulevard
Building A
Mt. Pleasant, SC 29464

Lead Counsel for ZAI Claimants